

CLAIMS

1. A vaginal mucoadhesive composition for single dose administration, comprising sertaconazole or one of its pharmaceutically acceptable salts wherein the proportion of sertaconazole or the salt is higher than 2 % and does not exceed 10 %.
2. The composition of claim 1, wherein the proportion of sertaconazole or the salt is from 3 to 10%.
3. The composition of claim 1 or 2, which is a cream or a gel.
4. The composition of any one of claims 1 to 3, wherein the pharmaceutically acceptable salt is sertaconazole nitrate.
5. The composition of claim 4, wherein the proportion of sertaconazole nitrate is from 6 to 7%.
6. The composition of any one of claims 3 to 5, wherein the cream contains lipophilic excipients, mucoadhesive excipients and one or more preservatives, and the gel dosage form contains mucoadhesive excipients and one or more preservatives.
7. The composition of claim 6, wherein the lipophilic excipients are selected from glyceryl stearates and their derivatives, ketostearyl alcohols, polyoxyethylene glycol ethers of n-alcohols, liquid paraffin, lecithin oil, glycerol and the like.

8. The composition of claim 7, wherein the lipophilic excipients are present in a total proportion of from 10 to 40%.

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9. The composition of claim 8, wherein the lipophilic excipients are present in a total proportion of from 30 to 35%.

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10. The composition of claim 6, wherein the mucoadhesive excipients are selected from cellulose polymers, gelatin, colloidal anhydrous silica and polyacrylic acid polymers.

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11. The composition of claim 10, wherein the mucoadhesive excipients are polyacrylic acid polymers.

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12. The composition of claim 11, wherein the polyacrylic acid polymers form a mixture of polyacrylic acid polymer cross-linked with divinyl glycol and acrylic acid polymer cross-linked with sucrose or pentaerythritol allyl esters.

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13. The composition of claim 12, wherein the mixture of polyacrylic acid polymer cross-linked with divinyl glycol and acrylic acid polymer cross-linked with sucrose or pentaerythritol allyl esters are present in a proportion of from 0.1 to 3%.

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14. The composition of claim 13, wherein the mixture of polyacrylic acid polymer cross-linked with divinyl glycol and acrylic acid polymer cross-linked with

sucrose or pentaerythritol allyl esters are present in a proportion of from 1 to 1.5%.

5 15. The composition of claim 6, wherein the preservatives are selected from parabens, benzoic acid, sorbic acid, boric acid and the like.

10 16. The composition of claim 15, wherein the preservatives are present in a total proportion of from 0.01 to 0.3%.

15 17. The composition of claim 16, wherein the preservatives are present in a total proportion of from 0.1 to 0.2%.

18. The composition of any one of the preceding claims, wherein its content is packed in a single-dose applicator.

20 19. The composition of claim 18, wherein its capacity is from 4 to 6 ml.

25 20. The composition of claim 19, wherein its capacity is 5 ml.

30 21. A kit comprising the composition according to claims 1-20, and a cream composition for vulvar application containing sertaconazole or one of its pharmaceutically acceptable salts.

22. The kit of claim 21, wherein the pharmaceutically acceptable salt is sertaconazole nitrate.

23. The kit of claim 22, wherein sertaconazole nitrate is present in a proportion of from 1 to 3%.

24. The kit of claim 23, wherein sertaconazole nitrate is present in the proportion of 2%.

25. Use of the composition according to claims 1 to 20 for the manufacture of a pharmaceutically acceptable dosage form for the treatment of vulvovaginal candidiasis of the vagina.

26. A method for treating vulvovaginal candidiasis, wherein the composition of claim 1 is administered into the vagina of a subject in need of such treatment in a single dose.

27. The method of claim 26, wherein additionally a composition containing sertaconazole or one of its pharmaceutically acceptable salts is applied to the vulva in single or repeated dose.